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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,396	09/26/2003	Daniel V. Santi	300622010900	9173

7590 12/20/2005
TED APPLE (TOWNSEND AND TOWNSEND AND CREW)
379 LYTTON AVENUE
PALO ALTO, CA 94301

EXAMINER

ROBINSON, HOPE A

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,396

Applicant(s)

SANTI ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Restriction/Election

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 24, 39 and 62 are drawn to a synthetic gene, vector, cell and method of making polyketide.

Group II, claim(s) 16-21 are drawn to a gene library.

Group III, claim(s) 22-23, 25-26 and 29 are drawn to a cloning vector.

Group IV, claim(s) 27-28 are drawn to a vector.

Group V, claim(s) 30-32 are drawn to a composition.

Group VI, claim(s) 33 is drawn to a vector with a selectable marker.

Group VII, claim(s) 34-37, 40-43 and 65-66 are drawn to a method of joining a series of DNA units using a vector pair.

Group VIII, claim(s) 38 and 67-68 are drawn to a method of joining several DNA units in a sequence.

Group IX, claim(s) 44-45 are drawn to a method of making a synthetic gene.

Art Unit: 1656

Group X, claim(s) 46-48 are drawn to a method for identifying restriction enzyme recognition sites.

Group XI, claim (s) 49-50 are drawn to a method for high throughput synthesis.

Group XII, claim (s) 51-58 are drawn to a method for designing a synthetic gene.

Group XIII, claim(s) 59-60 are drawn to a method for analyzing a nucleotide sequence of a synthon.

Group XIV, claim(s) 61 is drawn to a system for high throughput synthesis of synthetic genes.

Group XV, claim(s) 63-64 are drawn to an open reading frame vector.

2. The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: because under PCT Rule 13.1 applicant is entitled to the first product, method of using and making said product. Further the technical feature of Group I is a synthetic gene corresponding to a naturally occurring gene encoding a polypeptide segment wherein said synthetic gene is less than 90% identical to said naturally occurring gene. This technical feature is not a special technical feature because it does not escape the prior art as Wingfield et al. (Protein Science, vol. 6, pages 1653-1660, 1997) teach DNA encoding residues 27-149 of transmembrane glycoprotein gp41 from SIVmac239 containing two non-naturally occurring mutations: C86A and C92A (see page 1658, column 1). The gene taught by Wingfield et al. is less than 90% identical to the naturally occurring gene because it is

Art Unit: 1656

missing the N-terminal 26 residues. Applicant has defined a "synthetic gene" on page 17 of the specification as being "a gene comprising a polypeptide segment-coding sequence not found in nature, where the polypeptides segment-encoding sequence encodes a polypeptide or fragment or domain of at least about...50 amino acid residues length". The gene taught by Wingfield et al. encodes a fragment of gp41 (the N-terminus if missing) that is greater than 50 amino acids and contains a sequence that is not found in nature since residues 86 and 92 are mutated *in vitro*. As Wingfield et al. anticipates Group I, these inventions are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

Art Unit: 1656

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope A. Robinson, MS 

Patent Examiner

**HOPE ROBINSON
PATENT EXAMINER**